Objectives: This study evaluated the efficacy and safety of FEN compared with placebo (PBO) and adalimumab (ADA), in combination with background methotrexate (MTX), in patients (pts) with rheumatoid arthritis (RA).

Methods: This multicenter, randomized, double-blind Phase 2 study included pts with moderate-to-severe active RA with an inadequate response to MTX (MTX-IR, Cohort 1) or TNF inhibitors (TNF-IR, Cohort 2). Cohort 1 pts were randomized to FEN at 50 mg QD (FEN-50), 150 mg QD (FEN-150), 200 mg BID (FEN-200), 40 mg ADA injections SC Q2W, or PBO. Cohort 2 pts were randomized to FEN-200 or PBO. Key efficacy endpoints evaluated the proportion of pts with an ACR50 response at Week 12 (W12), comparing FEN doses to PBO (both cohorts) and to ADA (Cohort 1).

Results: Cohort 1 (FEN-50, n=40; FEN-150, n=109; FEN-200, n=110; PBO, n=110; ADA, n=111) and Cohort 2 (FEN-200, n=48; PBO, n=50) demographics and disease characteristics were balanced, and ~90% of pts per arm completed the study. In Cohort 1, ACR50 response rates increased with increasing FEN dose (18%, 28%, and 35% for FEN-50, FEN-150, and FEN-200, respectively). FEN-150 (28%, p=0.0164) and FEN-200 (35%, p=0.0003) were superior to PBO (15%), and numerically similar to ADA (36%). In Cohort 2, the response for FEN-200 was higher than PBO (25% vs. 12%) (Table 1). Adverse events (AEs) were generally balanced across Cohort 1; there were 9 serious AEs in 7 pts and one death in the FEN-200 group. In Cohort 2, more pts in the PBO arm reported AEs, and no serious AEs were reported.

Conclusion: FEN demonstrated higher efficacy rates than PBO for ACR50 at W12 in both MTX-IR and TNF-IR populations, and was similar to ADA in MTX-IR pts. The overall safety profile of FEN was acceptable.

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OP0026

A PHASE 3 STUDY OF THE EFFICACY AND SAFETY OF PEFICITINIB (ASP015K) IN PATIENTS WITH RHEUMATOID ARTHRITIS WHO HAD AN INADEQUATE RESPONSE TO METHOTREXATE

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Background: Peficitinib (ASP015K), a novel oral JAK inhibitor, demonstrated efficacy as once-daily monotherapy in patients with moderate-to-severe rheumatoid arthritis (RA) in a phase 2b study (NCT01649999)¹.

Objectives: To evaluate the efficacy and safety of peficitinib-methotrexate (MTX) combination in patients with RA who had an inadequate response to MTX.

Methods: This multicentre, randomised, double-blind, parallel-group, placebo (PBO)-controlled, phase 3 study (NCT02305849) was conducted in Japan. Patients had RA diagnosed within the past 10 years (1987 ACR or 2010 ACR/EULAR criteria), active disease (≥6 tender and painful joints and ≥6 swollen joints, using 68 and 66-joint assessment respectively; CRP ≥1.0 mg/dL; bone erosion; and ACPA or RF positivity) and inadequate response to MTX (administered for ≥90 days; ≥8 mg/week for ≥28 days prior to baseline). Patients were randomised 1:1:1 to 52-week MTX plus PBO, peficitinib 100 mg/day or peficitinib 150 mg/day. At week 12, inadequate responders in the PBO group (<20% improvement from baseline in tender and swollen joint counts) were switched (under blinded conditions) to peficitinib 100/150 mg until end of treatment. Remaining patients in the PBO group were switched (under blinded conditions) to peficitinib at week 28. Concomitant stable MTX dose (≤16 mg/week) was mandatory.

Primary efficacy variables were ACR20 response rate at week 12/early termination (ET) and change from baseline in modified Total Sharp score (mTSS) at week 28/ET.

Table 1 Primary and selected secondary efficacy endpoints at week 12/ET

Result	Week 12/ET			Week 28/ET		
	PBO	Peficitinib 100 mg/day	Peficitinib 150 mg/day	PBO	Peficitinib 100 mg/day	Peficitinib 150 mg/day
ACR20, n/N (%)	37/170 (21.8)	102/174 (58.6)***	112/174 (64.4)***	50/170 (29.4)	129/174 (74.1)***	137/174 (78.7)***
ACR50, n/N (%)	13/170 (7.6)	52/174 (29.9)***	80/174 (46.0)***	19/170 (11.2)	88/174 (50.6)***	103/174 (59.2)***
ACR70, n/N (%)	4/170 (2.4)	21/174 (12.1)***	43/174 (23.6)***	10/170 (5.9)	47/174 (27.0)***	70/174 (40.2)***
Mean (SD) CRP change from baseline, mg/dL	-0.001 (2.038)	-1.499 (1.855)***	-1.421 (2.182)***	-0.041 (2.399)	-1.649 (2.165)***	-1.625 (2.236)***
Mean (SD) ESR change from baseline, mm/h	-2.42 (19.71)	-18.90 (19.85)***	-22.17 (22.79)***	-3.26 (22.68)	-24.51 (23.67)***	-26.21 (24.58)***
SDAS28-CRP <2.6, n/N (%)	13/169 (7.7)	54/172 (31.4)***	60/171 (35.1)***	20/169 (11.8)	86/172 (50.0)***	86/171 (50.3)***
Mean (SD) SDAS28-CRP change from baseline	-0.51 (1.10)	-1.70 (1.20)***	-2.09 (1.33)***	-0.64 (1.33)	-2.27 (1.31)***	-2.56 (1.38)***
Mean (SD) change from baseline in patient's assessment of pain, 100 mm VAS	6.64 (25.22)	-21.09 (27.04)***	-26.87 (26.65)***	7.61 (27.81)	-26.33 (28.22)***	-32.23 (27.59)***
SDAI remission (SDAI score ≤3.3), n/N (%)	1/169 (0.6)	12/172 (7.0)**	24/171 (14.0)***	6/169 (3.6)	36/172 (20.9)***	37/171 (21.6)***
Result	Week 28/ET			Week 52/ET		
	PBO	Peficitinib 100 mg/day	Peficitinib 150 mg/day	PBO	Peficitinib 100 mg/day	Peficitinib 150 mg/day
Mean (SD) mTSS change from baseline ^a	3.37 (5.46)	1.62 (4.23)***	1.03 (2.86)***	6.27 (10.18)	2.12 (5.83)***	1.54 (4.11)***
Patients achieving change from baseline mTSS ≤0.5 ^b , n/N (%)	70/153 (45.8)	110/164 (67.1)***	119/164 (72.6)***	65/153 (42.5)	105/164 (64.0)***	113/164 (68.9)***

Last Observation Carried Forward imputation method was used, except for mTSS. Statistical testing was performed for peficitinib 100 mg, and 150 mg, compared with PBO.

p<0.01 vs PBO; *p<0.001 vs PBO, according to Fisher's Exact test for ACR20, ACR50, ACR70, SDAS28-CRP <2.6, SDAI remission, and mTSS change from baseline ≤0.5; analysis of covariance for CRP, ESR, SDAS28-CRP, and patient's assessment of pain; and rank analysis of covariance for mTSS change from baseline. Closed testing procedure was used for multiplicity adjustment in the primary analysis.

^aFor the calculation of mTSS, patients who discontinued at or before week 28 or were switched from PBO to peficitinib at week 12 due to lack of efficacy, week 28/ET mTSS was extrapolated using linear extrapolation method based on the mTSS at baseline and early termination or week 12 (day 85) (before switching). For patients who discontinued at or before week 52 or switched to receive peficitinib instead of placebo at week 12 or week 28, mTSS at week 52/ET was extrapolated using a linear extrapolation method based on mTSS at baseline and early termination, week 12 (Day 85) or week 28 (Day 197) (before switching).

mTSS=modified Total Sharp score; SD=standard deviation; SDAI=simplified disease activity index; VAS=visual analog scale.

Table 2 Treatment-emergent adverse events

	PBO (N=170)	Peficitinib 100 mg/day (N=174)	Peficitinib 150 mg/day (N=174)	Peficitinib 100 mg/day + 150 mg/day (N=348)
Event, n (%), Week 0-12				
Any AE	84 (49.4)	89 (51.1)	104 (59.8)	193 (55.5)
Drug-related AE ^a	47 (27.6)	57 (32.8)	80 (46.0)	137 (39.4)
Death	0	0	0	0
SAE	4 (2.4)	5 (2.9)	3 (1.7)	8 (2.3)
Drug-related SAE ^a	2 (1.2)	3 (1.7)	3 (1.7)	6 (1.7)
Grade ≥3 AE ^b	8 (4.7)	9 (5.2)	16 (9.2)	25 (7.2)
AE leading to permanent discontinuation of study drug	7 (4.1)	5 (2.9)	5 (2.9)	10 (2.9)
Serious infection	0	3 (1.7)	1 (0.6)	4 (1.1)
Herpes zoster-related disease	0	2 (1.1)	3 (1.7)	5 (1.4)
Malignancy	0	0	0	0
Incidence rate per 100 patient-years (95% confidence interval), overall study period^c				
	PBO (N=170)	Peficitinib 100 mg/day (N=174)	Peficitinib 150 mg/day (N=174)	Peficitinib total (N=496) ^d
Serious infection ^e	0.0	3.8 (1.7, 8.4)	3.7 (1.7, 8.3)	3.4 (2.0, 5.8)
Herpes zoster-related disease	3.2 (0.8, 12.8)	8.3 (4.8, 14.3)	3.8 (1.7, 8.4)	5.7 (3.8, 8.6)
Malignancy	1.6 (0.2, 11.3)	0.6 (0.1, 4.4)	0.0	0.2 (0.0, 1.7)

^aPossibly or probably related to study drug, as assessed by the investigator, or records where relationship is missing.

^bBased on NCI-CTCAE grade: grade 3=severe or medically significant, grade 4=life threatening, grade 5=death related to AE.

^cPatient-years covers from initial dose up to first incidence of AE for patients who had at least one event, otherwise, the duration of the patients are summed as from initial dose through follow-up. Incidence rate was calculated as 100 x number of patients who had at least one incidence / total patient-year.

^dIncludes AEs that occurred after initial peficitinib dosing, and after switching from PBO to peficitinib 100 mg/day or 150 mg/day.

^eDefined as an AE belonging to the system organ class of 'infections and infestations' and regarded as serious. AE=adverse event; SAE=serious adverse event.

Results: 519 patients were treated: PBO (n=170), peficitinib 100 mg (n=175) and peficitinib 150 mg (n=174). At week 12, 75 PBO-treated patients were switched to peficitinib 100 mg (n=37) and 150 mg (n=38) due to inadequate response. At week 12/ET, peficitinib showed superior efficacy vs PBO with respect to symptoms and inflammatory markers (Table 1). At weeks 28 and 52, peficitinib significantly reduced the mean mTSS change from baseline vs PBO (Table 1). Week 0-12 safety results were similar for PBO and peficitinib (Table 2). For the overall study period, incidence rate of serious infections per 100 patient-years was higher with peficitinib 100 mg/150 mg than PBO (Table 2).

Conclusion: In patients with RA who had an inadequate response to MTX, peficitinib 100 mg/day and 150 mg/day demonstrated significant superiority vs PBO in reducing RA symptoms and suppressing joint destruction, according to primary efficacy variables (ACR response and change in mTSS). Peficitinib 100 mg and 150 mg showed acceptable safety and tolerability, with no new safety signals compared with other JAK inhibitors.

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OP0027

EFFECT OF SHORT-TERM METHOTREXATE DISCONTINUATION ON THE DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS: POSTHOC-ANALYSIS OF TWO RANDOMIZED CLINICAL TRIALS

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Background: Patients with rheumatoid arthritis (RA) require a continuous, potentially life-long immune suppression with disease modifying antirheumatic drugs (DMARDs) including methotrexate (MTX). However, in special circumstances such as life-threatening infections, vaccinations or major surgeries, use of MTX should be minimized to restore the treatment-associated immune suppression. While a long-term or permanent discontinuation of MTX is associated with a

disease flare or relapse, the effect of short-term discontinuation on disease activity has not been fully elucidated.

Objectives: To investigate the effect of short-term discontinuation of MTX on the disease activity in patients with RA on stable dose of MTX.

Methods: This is a posthoc analysis of 2 randomized controlled studies investigating effect of MTX discontinuation for 2 weeks or 4 weeks on vaccine response to seasonal influenza vaccination in patients with RA. In the 4-week discontinuation study, 54 patients continued MTX and 44 patients discontinued it for 4 weeks before vaccination with trivalent seasonal influenza vaccine. In the 2-week discontinuation study, 159 patients continued MTX and 161 patients held it for 2 weeks after a seasonal quadrivalent influenza vaccine. Disease activity (DAS28 change, DAS28 flare rate and flare-free survival) was compared between the patients who continued MTX and those held it. A RA flare was defined as an increase in DAS28 of >1.2 or >0.6 if the baseline DAS28 was ≥3.2.

Results: In the 4-week MTX-hold group, the mean DAS28 increased at the 4 weeks after MTX discontinuation by 0.38 ± 0.94 and then improved back to baseline after reintroduction of MTX, whereas the mean DAS28 in the MTX-continue group remained stable over time (Figure 1A). The overall flare-free survival during 20 weeks did not differ between the groups (log rank $p=0.142$) (Figure 1B). However, numerically more patients in the MTX-hold group experienced a flare than those in the MTX-continue group during the 4-weeks MTX discontinuation (20.5% vs. 7.4%, $p=0.058$). After resuming MTX, the flare rate did not differ between the groups up to 20 weeks of observations (Figure 1C). A temporary MTX discontinuation for 2 weeks was not associated with any clinically meaningful change in disease activity.

Figure 1. Changes in disease activity of rheumatoid arthritis after MTX discontinuation over time. (A) DAS28-CRP and (B) RA flare free survival in the MTX continue and the MTX hold group were depicted. (C) RA flare rates over time were shown. MTX, methotrexate.

Conclusion: A short-term MTX discontinuation for 2 weeks is safe without any change in disease activity. A 4-week MTX discontinuation is associated with transient increase in disease activity without affecting long-term outcomes.

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OP0028

POST-APPROVAL COMPARATIVE SAFETY STUDY OF TOFACITINIB AND BIOLOGIC DMARDs: FIVE-YEAR RESULTS FROM A US-BASED RHEUMATOID ARTHRITIS REGISTRY

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Background: Tofacitinib is an oral JAK inhibitor for the treatment of rheumatoid arthritis (RA). Real-world data (RWD) complement clinical trial data in assessing